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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,022	06/18/2007	Ching-Shih Chen	22727/04418	4927

24024 7590 04/29/2010

CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER
OH, TAYLOR V

ART UNIT	PAPER NUMBER
1625	

NOTIFICATION DATE	DELIVERY MODE
04/29/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@calfee.com
dcunin@calfee.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,022	CHEN ET AL.	
	Examiner	Art Unit	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6-17 and 20-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *12-15,22 and 23* is/are allowed.

6)☒ Claim(s) *1,3,7,8,16,17,20,21 and 24* is/are rejected.

7)☒ Claim(s) *6 and 9-11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/06/06* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Final Rejection

The Status of Claims

Claims 1,3, 6-17, and 20-24 are pending.

Claims 1,3, 7-8, 16-17, 20-21, and 24 are rejected.

Claims 6, 9-11 are objected.

Claims 12-15, and 22-23 are allowable.

Claim Objections

Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9-11 are objected to because of the following informalities:

In claim 9, the followings compounds , 2-Propyl-pentanoic acid {4-[2-amino-phenylcarbamoyl)-methyl]-phenyl}-amide; 2-Propyl-pentanoic acid {4-[2-amino-phenylcarbamoyl)-ethyl]-phenyl}-amide;

2-Propyl-pentanoic acid {4-2-(2-amino-phenylcarbamoyl)-vinyl]-phenyl}- amids are recited.

In claim 10, the followings compound,

N-(2-Amino-phenyl)-4-[(4-phenyl-butyrylamino-methyl]-benzamide, is recited.

In claim 11, the followings compounds,

N-(2-Amino-phenyl)-4-[(2-phenyl-butyrylamino-methyl]-benzamide, N-(2-Amino-phenyl)-4-[(3-phenyl-butyrylamino-methyl]-benzamide, are recited.

All the compounds in the claims lack of one of the parentheses.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

I. Applicants' argument filed 2/24/10 have been fully considered but they are not persuasive.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of Claims 1-25 under 35 U.S.C. 112, second paragraph, has been withdrawn; however, there are still some issues to be resolved in the amendment in spite of the revised claims 1 and 8.

In claims 1 and 8, the phrases " an aliphatic group including" and " an aromatic group including" are recited. These expressions are vague and indefinite because the term" including" does not specify what has been excluded from the aliphatic group and

the aromatic group; the skilled artisan in the art is unable to figure out what is excluded from them. The examiner recommends to change from "including " to "having." Appropriate correction is required.

In claim 8, the phrase " an aromatic group including from 3 to 14 carbons" is recited. This expression is vague and indefinite because the aromatic group has a minimum requirement of six carbon atoms. Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of Claims 18-19 under 35 U.S.C. 112, first paragraph, has been withdrawn due to the cancellation of the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of Claims 18-19 provisionally on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 36-45 of copending Application No. 12/361,626 has been withdrawn due to the cancellation of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1, 4-5, 7-8, 16-20 under 35 U.S.C. 102(a) as being anticipated clearly by Sato (WO 03/070691) has been withdrawn due to the cancellation of the claims.

The rejection of Claims 1-2, 7, and 16-17,20 under 35 U.S.C. 102(b) as being anticipated clearly by Bertolini et al (US 6,034,096) has been withdrawn due to the cancellation of the claims.

The rejection of Claims 1-2 , 6, and 16-20 under 35 U.S.C. 102(b) as being anticipated clearly by Manfred Jung (Current Medicinal Chemistry 2001, 8,1505-1511) has been withdrawn due to the cancellation of the claims.

In view of the revised claims 1 and 8, and 21, the rejections are applied to the claims in the followings.

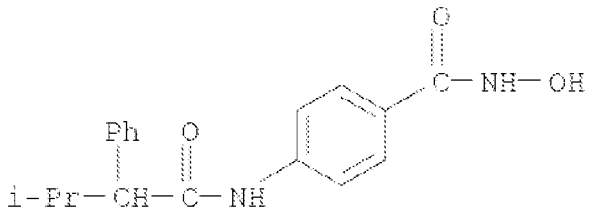
1. Claims 1,3, 7-8, 16-17,20-21 are rejected under 35 U.S.C. 102(a) as being anticipated clearly by Cumming et al (US 20030091623).

Cumming et al discloses the following compounds and their compositions(see abstract) :

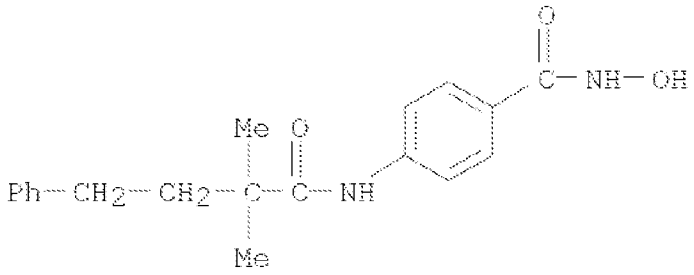
AB The invention relates to a pharmaceutical composition and oral dosage forms comprising an histone deacetylase (HDAC) inhibitor in combination with an enhancer to promote absorption of the HDAC inhibitor at the gastrointestinal tract cell lining. The enhancer is a medium chain fatty acid or a medium chain fatty acid derivative having a carbon chain length of from 6 to 20 carbon atoms. Preferably, the solid oral dosage form is a controlled release dosage form such as a delayed release dosage form. Thus, granules comprising 61.05% parnaparin sodium, 33.95% sodium caprate and 5% polyvinylpyrrolidone were prepared and administered orally to humans. The mean delivery of parnaparin, as measured by plasma anti-factor Xa levels, was considerably higher from the solid dosage form than that from the corresponding solution dosage.

IT 854779-93-4 854779-95-6
RL: PAC (Pharmacological activity); PKT (Pharmacokinetics); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(controlled release solid oral dosage form comprising a histone deacetylase inhibitor and a medium chain fatty acid derivative as an absorption enhancer)

RN 854779-93-4 CAPLUS
CN Benzeneacetamide, N-[4-[(hydroxyamino)carbonyl]phenyl]-α-(1-methylethyl)- (CA INDEX NAME)



RN 854779-95-6 CAPLUS
CN Benzenebutanamide, N-[4-[(hydroxyamino)carbonyl]phenyl]-α,α-dimethyl- (CA INDEX NAME)



This is identical with the claims.

Claim Rejections - 35 USC § 103

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

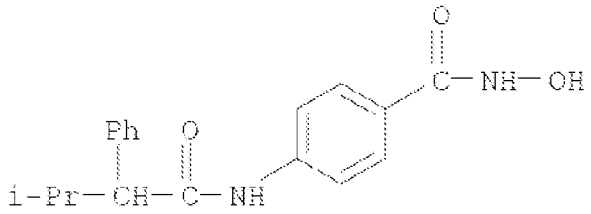
2. Claims 21 and 24 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cumming et al (US 20030091623).

Cumming et al discloses the following compounds(see abstract) :

AB The invention relates to a pharmaceutical composition and oral dosage forms comprising an histone deacetylase (HDAC) inhibitor in combination with an enhancer to promote absorption of the HDAC inhibitor at the gastrointestinal tract cell lining. The enhancer is a medium chain fatty acid or a medium chain fatty acid derivative having a carbon chain length of from 6 to 20 carbon atoms. Preferably, the solid oral dosage form is a controlled release dosage form such as a delayed release dosage form. Thus, granules comprising 61.05% parnaparin sodium, 33.95% sodium caprate and 5% polyvinylpyrrolidone were prepared and administered orally to humans. The mean delivery of parnaparin, as measured by plasma anti-factor Xa levels, was considerably higher from the solid dosage form than that from the corresponding solution dosage.

IT 854779-93-4 854779-95-6
RL: PAC (Pharmacological activity); PKT (Pharmacokinetics); THU (Therapeutic use); BIOL (Biological study); USES (Uses)
(controlled release solid oral dosage form comprising a histone deacetylase inhibitor and a medium chain fatty acid derivative as an absorption enhancer)

RN 854779-93-4 CAPLUS
CN Benzeneacetamide, N-[4-[(hydroxyamino)carbonyl]phenyl]-α-(1-methylethyl)- (CA INDEX NAME)



The instant invention, however, differs from the prior art in that the composition enriched in the S-stereoisomer as compared to the R-stereoisomer is unspecified.

Even so, it is a well-known fact in the art that the chiral compound has two forms (S and R) of stereoisomers; furthermore, it is within knowledge of the skilled artisan in the art to be able to separate them as well as modify its composition whether or not the composition can be enriched in the S-stereoisomer as compared to the R-stereoisomer. Therefore, if the skilled artisan in the art had desired to form the composition to be enriched in the S-stereoisomer as compared to the R-stereoisomer , it would have been obvious to the skilled artisan in the art to be motivated to manipulate the composition containing both two forms (S and R) of stereoisomers depending on the intended purpose of the skilled artisan. This is because such a practice is within the purview of the skilled artisan in the art.

Applicants' Argument

3. Applicants argue the following issues:

i. Jung does not describe the compounds of the claims as presently amended; the claims recite compounds with an aliphatic or aromatic group at A that includes 3 to 14 carbons, which is at least two carbons more than provided by Jung at this position.

Applicants' arguments have been noted, but the arguments are not found to be persuasive.

Regarding the first argument, the Examiner has noted applicants' argument. However, although the previous rejection based on the prior art Including Jung had been withdrawn, as shown in the above, there are still some issues to be resolved in the amendment in spite of the revised claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taylor Victor Oh/
Primary Examiner, Art Unit 1625

4/24/10